IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

GEORGIA COLLEGE OF EMERGENCY PHYSICIANS and BRETT CANNON, M.D., Plaintiffs, vs. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, OFFICE OF PERSONNEL MANAGEMENT, and the CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES, Defendants.	CIVIL ACTION NO. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Georgia College of Emergency Physicians ("GCEP") and Brett Cannon, M.D., by and through their attorneys, bring this action for declaratory and injunctive relief against defendants the United States Department of Health and Human Services, Department of Labor, Department of the Treasury, Office of

Personnel Management, and the current heads of those agencies in their official capacities, and allege as follows:

INTRODUCTION

1.

This is an action under the Administrative Procedure Act ("APA") to set aside specific and limited provisions of the interim final rule issued by the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, and the Office of Personnel Management (collectively, the "Departments") in violation of their statutory authority. The rule, entitled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021) ("September Rule"), implements provisions of the federal surprise medical billing law, the No Surprises Act, Pub. L. 116-260 (the "Act").[1] The Act was passed

[1] The Act made parallel amendments to provisions of the Public Health Service ("PHS") Act, which is enforced by the Department of Health and Human Services ("HHS"); the Employee Retirement Income Security Act ("ERISA"), which is enforced by the Department of Labor; and the Internal Revenue Code ("IRC"), which is enforced by the Department of the Treasury. These Departments, along with the Office of Personnel Management ("OPM") (which oversees health benefits plans offered by carriers under the Federal Employees Health Benefits Act), issued the September Rule. Many of the regulations adopted in the September Rule are parallel provisions that apply, as relevant, to group health plans and health insurance issuers offering group or individual health insurance coverage.

on December 27, 2020, as part of the Consolidated Appropriations Act, 2021, and its requirements generally go into effect on January 1, 2022.

2.

GCEP strongly supports Congress's goal of protecting patients from surprise billing, including the compromise Congress reached in the Act—shielding patients from unexpected medical bills while also enabling physicians and hospitals ("providers"), on the one hand, and group health plans or commercial health insurance carriers ("insurers"), on the other, to determine fair payment among themselves. In passing the Act, Congress established an independent dispute resolution ("IDR") process which removed patients from the middle of negotiations between providers and insurers and intentionally balanced the scale between providers and insurers.[2] The Departments' implementation of the Act in the September Rule, however, deviates from Congress's balanced design in a critical respect: the Rule places a heavy thumb on the scale during the independent arbitration process in a way that directly conflicts with the statutory text. The

[2] Press Release, House Ways & Means Comm., Neal and Brady Release Legislative Text of Surprise Medical Billing Proposal (Feb. 7, 2020), https://waysandmeans.house.gov/media-center/press-releases/neal-and-brady-release-legislative-text-surprise-medical-billing ("Our bipartisan approach differs from other proposals in that . . . we create a *more balanced negotiation process* to encourage all parties to resolve their reimbursement differences before using the streamlined and fair dispute resolution process." (emphasis added)).

Departments reached this atextual result, moreover, without first providing notice or receiving the benefits of the public's views, as the law requires.

3.

The No Surprises Act was the result of "a long-fought and negotiated bipartisan and bicameral compromise to protect patients by ending surprise billing." 166 Cong. Rec. H7290, H7291 (Dec. 21, 2020). A critical component of that compromise is the Act's IDR process. It protects patients from surprise medical bills by limiting the amount a patient can be billed by a provider who is not in the network supplied by their insurer. That limit is the amount of cost-sharing the patient would pay to a provider in their insurer's network. Providers not in the network are required to negotiate reasonable payment directly with the patient's insurer. If that negotiation is unavailing, the Act provides for binding "baseball-style" arbitration before a certified arbitrator (or, as the Act calls it, an "IDR entity," and hereafter referred to as either "arbitrator" or "IDR entity"). The provider and insurer submit to the arbitrator the payment amounts requested or offered, and the arbitrator must select one as the appropriate payment rate. This system was designed to ensure that the parties submit their most-reasonable and best-supported offers.

4.

Congress expressly enumerated in detail the factors that an arbitrator "shall" consider in determining which offer to select. Consistent with its goal of creating a balanced, independent process that protects patients by keeping them out of negotiations between providers and insurers, the Act did not assign any one statutory factor presumptive weight. Rather, Congress directed IDR entities to consider all of the enumerated factors, thereby leaving it to each IDR entity to determine how to best weigh the various factors in light of all the facts and circumstances presented in a particular case. Indeed, key House and Senate Committee Leaders stated when announcing the final Act:

> "We have reached a bipartisan, bicameral deal in principle to protect patients from surprise medical bills and promote fairness in payment disputes between insurers and providers . . . ."
>
> . . . .
>
> If the parties choose to utilize the IDR process, both parties would each submit an offer to the independent arbiter. When choosing between the two offers[,] the arbiter is required to consider the median in-network rate, information related to the training and experience of the provider, the market share of the parties, previous contracting history between the parties, complexity of the services provided, and any other information submitted by the parties.

Press Release, House Ways & Means Comm., Congressional Committee Leaders Announce Surprise Billing Agreement (Dec. 11, 2020),

https://waysandmeans.house.gov/media-center/press-releases/congressional-committee-leaders-announce-surprise-billing-agreement.

5.

In contravention of clear Congressional intent, the Departments read into the Act via the September Rule a "rebuttable presumption" that requires IDR entities to give outsized weight to a single statutory factor—the "qualifying payment amount" ("QPA"). The QPA is generally the median of the payor's contracted rates for the relevant item or service, *as exclusively calculated by the payor*.

6.

To effectuate this presumption, the September Rule erects two separate barriers to an arbitrator's consideration of the other statutorily mandated factors.

a) *First*, the September Rule provides that the arbitrator may not consider any of the non-QPA statutory factors unless a party submits "credible information" about them, 45 C.F.R. § 149.510(c)(4)(iii)(B), and the Rule defines "credible information" to require the arbitrator to skeptically analyze that information, *id.* § 149.510(a)(2)(v) (defining "credible information" as "information that upon *critical analysis* is worthy of belief and is trustworthy" (emphasis added)). In vivid contrast, the September Rule contains no such credibility requirement for the QPA

factor. In fact, the Departments affirmatively forbid the arbitrator from scrutinizing the QPA, commanding the IDR entity to take the insurer's proffered QPA as given. *See* 86 Fed. Reg. at 55,996 ("[I]t is not the role of the certified IDR entity to determine whether the QPA has been calculated by the [insurer] correctly[.]"). For clarity, Plaintiffs always assumed that parties would submit credible evidence and that arbitrators would take credibility into account in analyzing each of the statutorily mandated factors. Instead, Plaintiffs' objection is that the September Rule sets up a skeptical, one-sided evidentiary burden that is found nowhere in the Act and makes it more difficult for the arbitrator to fairly consider all six statutory factors as Congress intended.

b) *Second*, and more importantly, the September Rule provides that the arbitrator "*must* select the offer closest to the QPA" unless a party meets a heightened burden of proof found nowhere in the Act. 45 C.F.R. § 149.510(c)(4)(ii)(A) (emphasis added). Specifically, to overcome the presumption in favor of the QPA, a party must "clearly demonstrate[]" that the QPA is "materially different from the appropriate out-of-network rate." *Id.*

7.

In inventing these extra-statutory barriers, the Departments acted contrary to Congress's intentional compromise mandating that the arbitrator consider all enumerated factors without giving categorical priority to any single one. As a result, these provisions of the September Rule are manifestly unlawful and will unfairly skew IDR results in payors' favor by favoring the QPA, granting them a windfall they were unable to obtain in the legislative process. These provisions of the September Rule will simultaneously undermine providers' ability to obtain adequate reimbursement for their services to the detriment of both providers and the patients they serve.

8.

The principal architects of the Act have expressed their dissatisfaction with the September Rule, explaining that "the law provides for an IDR process overseen by an independent and neutral arbiter who must consider a number of factors equally in deciding whether to select the provider or [insurer]'s offer." Letter from Chairman Neal and Ranking Member Brady of the House Ways and Means Committee to Department Secretaries (Oct. 4, 2021) ("Neal and Brady Letter"), https://www.gnyha.org/wp-content/uploads/2021/10/2021.10.04-REN-KB-Surprise-Billing-Letter80.pdf.

9.

The Departments claim that theirs is the "best interpretation" of the Act. 86 Fed. Reg. at 55,996. But as the Act's principal architects explained, the September Rule "strays from the No Surprises Act in favor of an approach that Congress did not enact in the final law," given that "Congress deliberately crafted the law to avoid any one factor tipping the scales during the IDR process." Neal and Brady Letter. Remarkably, Chairman Neal and Ranking Member Brady also wrote that the September Rule "affronts the provisions enacted into law." *Id*. Amplifying these same concerns, a recent letter from 150 other members of Congress explained that the September Rule's presumption-based approach for determining payment rates "do[es] not reflect the way the law was written, do[es] not reflect a policy that could have passed Congress, and do[es] not create a balanced process to settle payment disputes." Letter from Members of Congress to Departments Secretaries (Nov. 5, 2021),

https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf.

10.

The September Rule will harm patients. *First*, the rule will encourage insurers to narrow the network of providers available to patients and potentially eschew providers with higher costs, including teaching and other hospitals that provide

trauma care, burn units, and neonatal intensive care services that are critical for their communities. Because insurers can now rely on the IDR process for an unfairly low rate, they will have little incentive to include providers with higher costs (and frequently higher quality and specialized services) in their network, all to the detriment of patients. In fact, one insurer, Blue Cross Blue Shield North Carolina, has already threatened to "terminate agreements" with providers who do not agree to lower rates in light of the new rule on the grounds that "the Interim Final Rules provide enough clarity to warrant a significant reduction in your contracted rate with Blue Cross NC." Letter from Mark Werner, Blue Cross Blue Shield of North Carolina, to Provider (Nov. 5, 2021), https://tinyurl.com/y3dfvtts. *Second*, undercompensating providers could, as the Departments recognized themselves, "threaten the viability of these providers [and] facilities," which "in turn, could lead to participants, beneficiaries[,] and enrollees not receiving needed medical care." 86 Fed. Reg. at 56,044. Essentially, this lawsuit seeks to preserve access to care, as the September Rule would reduce it. Congress did not intend that result.

11.

The Departments, moreover, denied Plaintiffs an opportunity to raise this issue because they elected to issue the regulation without the notice and comment process required by the APA. The IDR process is critical to ensuring that healthcare

providers can continue to provide medically necessary care and treatment to patients and be fairly and reasonably reimbursed for those services. The Departments understood the value of stakeholder engagement on this issue. In fact, during current HHS Secretary Xavier Becerra's confirmation hearing, he acknowledged "we [have] got to get this arbitration provision right."[3] Further, during an April 2021 congressional hearing on HHS's budget request, when asked whether HHS would give stakeholders advance notice and an opportunity to comment on regulations implementing the Act, Secretary Becerra responded: "coming from a background as the [California] attorney general where it was always important to take input whenever we would do rule making or whenever we would take any action, in court or otherwise, I can guarantee you at HHS, before we take any action, we'll take the comments necessary, hear from all the stakeholders to make sure what we're doing is based on the facts, the science, and the law. And I can guarantee you, sir, that you will find we will have gone through a robust process to get there."[4]

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[3] Confirmation hearing of Xavier Becerra before the Senate Health Committee (Feb. 23, 2021), https://www.c-span.org/video/?c4980098/user-clip-becerra-confirmation-comment-surprise-billing (at minute 1:41:06).

[4] Health and Human Services department Fiscal Year 2022 Budget Request before the House Appropriations Sub-Committee (Apr. 15, 2021), https://www.c-span.org/video/?c4980111/user-clip-becerra-statements-health-human-services-budget-request (at minute 49:06).

12.

This commitment was not honored. Instead, the Departments purported to find "good cause" for circumventing the notice and comment period. This decision was also unlawful. The good cause exception permits agencies to bypass their rudimentary obligation to provide notice and comment only in narrowly defined, exceptional circumstances where delay would cause serious harm. Such circumstances plainly do not exist here. When Congress enacted the Act on December 27, 2020, it directed the Departments to issue regulations implementing the IDR process by December 27, 2021, thereby giving the Departments an entire year to issue final regulations on this issue. Nevertheless, the Departments waited approximately nine (9) months, until late September 2021, to take action. The Departments cannot rely on their own delays to create an exigency justifying dispensing with notice and comment.

13.

Regardless, there was no exigency. The first arbitrations under the statute will not take place until approximately sometime in March 2022—over five (5) months after the September Rule was issued—affording ample time to allow notice and comment. In fact, by setting a December 27, 2021 deadline for IDR regulations, Congress itself determined that there would be sufficient lead time if final

regulations were issued by that date. Yet the Departments issued the September Rule a full three months in advance of this specific statutory deadline, when that time could have been used to provide notice and comment as required by the APA.

14.

The absence of any exigency is especially clear with regard to the critical issue here, the standard to be applied by IDR entities in determining the appropriate reimbursement amount for out-of-network services. Even if IDR entities needed the Departments' guidance on that issue—they do not as the Act provides all needed guidance—they would not need that guidance any sooner than March 2022, when the arbitrations are set to begin. The Departments could have provided notice and comment on the standard to be applied by IDR entities and issued a final rule well in advance of that date. Even if a final rule were not in place by then, the IDR process could function precisely as Congress designed it without the presumption the Departments engrafted onto that statute. There is no justification whatsoever for imposing such a requirement without providing notice and comment.

15.

Accordingly, the Court should set aside, as contrary to law and in excess of the Departments' statutory authority, the provisions of the September Rule requiring IDR entities to employ a presumption in favor of the QPA when determining a

payment amount in the IDR process. Additionally, the Court should vacate those provisions of the September Rule which were unlawfully issued without notice and comment and require the Departments to provide notice and comment before issuing any replacement rule.[5]

JURISDICTION AND VENUE

16.

The Court has jurisdiction over this action under 28 U.S.C. § 1331.

17.

The Court has the authority to grant the requested declaratory and injunctive relief under the Administrative Procedure Act and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

18.

Venue is proper in this judicial circuit under 28 U.S.C. § 1391(e) because this is an action against officers and agencies of the United States and at least one plaintiff resides in this district and no real property is involved in this action.

[5] The September Rule contains a number of other provisions, including those relating to providers' obligation to send uninsured and self-pay patients good faith estimates of expected charges, as well as provisions governing a patient-provider billing dispute resolution process. This lawsuit does not challenge any of these other provisions of the September Rule but only the aspects of the Rule that relate to its requirement that the arbitrator presumptively select the offer closest to the QPA.

PARTIES

19.

Plaintiff Georgia College of Emergency Physicians is a non-profit association that represents the interest of emergency physicians and their patients throughout Georgia. GCEP has its headquarters and principal place of business in Norcross, Georgia. It provides resources and information to assist emergency physicians in managing their practices and engaging in advocacy efforts with respect to legislation and regulations that impact emergency medicine. GCEP brings this suit on behalf of its provider members (generally emergency room physicians) whose reimbursement for out-of-network services will be determined through the IDR process and who will be harmed by the unlawful presumption the Departments imposed in the September Rule.

20.

Plaintiff Brett Cannon, M.D. is a licensed physician who resides and practices in Cobb County, Georgia. Dr. Cannon works through and has an ownership interest in The Bortolazzo Group, LLC, a physician group that partners with hospitals and health systems to provide, among other services, emergency medicine and has done so for over ten (10) years. Dr. Cannon is a member of GCEP.

21.

Defendant Department of Health and Human Services is an executive department of the United States headquartered in Washington, D.C.

22.

Defendant Department of the Treasury is an executive department of the United States headquartered in Washington, D.C.

23.

Defendant Department of Labor is an executive department of the United States headquartered in Washington, D.C.

24.

Defendant Office of Personnel Management is an executive agency of the United States headquartered in Washington, D.C.

25.

Defendant Xavier Becerra is the Secretary of Health and Human Services. Secretary Becerra is sued in his official capacity only.

26.

Defendant Janet Yellen is the Secretary of the Treasury. Secretary Yellen is sued in her official capacity only.

27.

Defendant Martin J. Walsh is the Secretary of Labor. Secretary Walsh is sued in his official capacity only.

28.

Defendant Kiran Ahuja is the Director of OPM. Director Ahuja is sued in his official capacity only.

FACTS

I. The No Surprises Act

A. Payment Framework Prior to Enactment of the No Surprises Act

29.

When a patient with private insurance coverage receives medical care from an in-network provider, the insurer pays the provider a negotiated, contracted rate for covered items or services. The patient is responsible for only the cost-sharing, such as a co-pay, that is required by her insurance plan. If there is a difference between a provider's billed charges and the contracted rate a provider receives from the insurer, the provider does not bill the patient for the difference. For this reason, the provider will negotiate her contract with the insurer to ensure that the contracted rate is a reasonable one.

30.

If, however, the insurer and provider have not signed a network agreement, the provider is out-of-network. When a patient receives care from an out-of-network provider, the provider submits a bill to the patient's insurer, and the insurer determines how much to pay the provider. The outstanding balance—the difference between what the provider billed and how much the insurer paid—may in many cases be billed to the patient. A bill from a provider to a patient for that amount is often referred to as a "balance bill."

31.

"Balance bills" are sometimes called "surprise bills" because they often result from situations in which the patient had no choice about her care, such as in the case of emergency care or care provided by an ancillary healthcare provider, like an out-of-network clinical lab.

B. Payment Framework Under the No Surprises Act

32.

The Act addresses scenarios in which surprise out-of-network billing occurs, such as emergency medical situations.

33.

In emergency situations, providers are required to treat patients regardless of ability to pay. *See, e.g.*, 42 U.S.C. § 1395dd(a) ("[I]f any individual (whether or not eligible for benefits under this subchapter) comes to the emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition, the hospital must provide for an appropriate medical screening examination within the capability of the hospital's emergency department[.]"); *Roberts v. Galen of Virginia Inc.*, 525 U.S. 249, 249 (1999) (per curiam) ("The Emergency Medical Treatment and Active Labor Act . . . places obligations of screening and stabilization upon hospitals and emergency rooms that receive patients suffering from an 'emergency medical condition.'").

34.

The Act mandates that, in situations where a patient has not consented to out-of-network care, a patient's cost-sharing requirement for emergency services furnished by an out-of-network provider, or non-emergency services furnished by an out-of-network provider at an in-network facility, will not exceed the cost-sharing

requirement that would apply if the services had been provided by an in-network provider or facility. 42 U.S.C. §§ 300gg-111(a)(1)(C)(ii), (b)(1)(A).[6]

35.

The actual cost-sharing amount is calculated using the "recognized amount." 42 U.S.C. §§ 300gg-111(a)(1)(C)(iii), (b)(1)(B). If there is no applicable All-Payer Model Agreement under section 1115A of the Social Security Act and no state law mandating a method to determine the total amount payable by a patient, the "recognized amount" is the QPA for the item or service. *Id.* § 300gg-111(a)(3)(H).[7]

36.

For each item or service, the QPA is generally the "median of the contracted rates recognized by the plan or issuer" as of January 31, 2019, in the same insurance market for "the same or similar item or service" provided by a provider "in the same or similar specialty and . . . geographic region," increased by inflation over 2019. 42 U.S.C. § 300gg-111(a)(3)(E)(i).

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[6] The Act also addresses surprise medical billing requirements for air ambulance providers. Those provisions are not at issue in this lawsuit.

[7] Pursuant to the Departments' July 2021 interim final rule, if there is no applicable All-Payer Model Agreement and no specified state law, the recognized amount is the lesser of the provider's billed charges or the QPA. "Requirements to Surprise Billing; Part I," 86 Fed. Reg. 36,872, 36,888 (July 13, 2021).

37.

Because the Act ensures that patients will not be billed in excess of their expected cost-sharing amounts, providers must look to insurers to ensure fair payment for their out-of-network services.

38.

The Act requires insurers to pay providers an "out-of-network rate," less the patient's cost-sharing requirement. 42 U.S.C. §§ 300gg-111(a)(1)(C)(iv)(II), (b)(1)(D). Unlike the cost-sharing requirement based upon the "recognized amount" paid by patients, Congress did not simply select the QPA as the appropriate "out-of-network" rate to be paid by insurers. Instead, the Act establishes a process for insurers and providers to carefully negotiate an appropriate "out-of-network" rate.

39.

If there is no applicable All-Payer Model Agreement and no relevant state law mandating a method to determine the total amount payable to an out-of-network provider, the Act authorizes insurers first to send the provider an initial payment or notice of denial of payment. 42 U.S.C. §§ 300gg-111(a)(1)(C)(iv)(I), (a)(3)(K). It can take a month or more from the date of service for the provider to receive the insurer's initial payment or notice of denial of payment. If the provider disagrees with the insurer's payment determination, the provider has thirty (30) days to enter

into a 30-day period of open negotiation with the insurer. *Id*. § 300-gg-111(a)(1)(C)(iv)(I), (a)(3)(K), (c)(1)(A). If the provider and insurer are unable to reach an agreement during the 30-day negotiation period, either party may, within four (4) days following the conclusion of the open negotiation period, initiate binding arbitration through the IDR process. *Id.* § 300gg-111(a)(3)(K), (c)(1)(B).[8]

40.

Given this timeline, for a service furnished on or after January 1, 2022, providers and insurers should reasonably expect to initiate the IDR process by approximately March 1, 2022.

C. The IDR Process

41.

Once the IDR process is initiated, the parties have three (3) business days to jointly select an arbitrator, or "certified IDR entity," to oversee the proceedings. 42 U.S.C. § 300gg-111(c)(4)(F)(i). If the parties fail to do so, the relevant agency will select the arbitrator no later than six (6) business days after the initiation of the IDR process.

[8] The parties may continue their negotiations during the arbitration process. If they reach an agreement on the out-of-network rate before the arbitrator determines an out-of-network rate, the agreed-upon rate controls. 42 U.S.C. § 300gg-111(c)(2)(B).

42.

The statute prescribes a "baseball-style" arbitration process whereby the provider and insurer submit their best and final offers for the amount each considers to be reasonable payment. Specifically, once an arbitrator is selected, the provider and insurer have ten (10) days to submit (1) an offer for a payment amount, (2) any information requested by the IDR entity, and (3) any additional information the party wishes the IDR entity to consider, including information relating to statutory factors the IDR entity must consider. 42 U.S.C. § 300gg-111(c)(5)(B), (C)(ii).

43.

The arbitrator then reviews the offers and "shall . . . select one of the offers" after "taking into account the considerations in subparagraph (C)" (the Subparagraph C Factors"). 42 U.S.C. § 300gg-111(c)(5)(A). The arbitrator must have "sufficient medical, legal, and other expertise and sufficient staffing" to select an appropriate out-of-network rate based on the Subparagraph C Factors. *Id*. § 300gg-111(c)(4)(A).

44.

In subparagraph C, titled "Considerations in determination," Congress mandates that, "[i]n determining which offer" to select, the arbitrator "shall consider":

> (I) the qualifying payment amounts . . . for the applicable year for items or services that are comparable to the qualified IDR item or

> service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; and
>
> (II) subject to subparagraph D, information on any circumstance described in clause (ii), such information as requested in subparagraph (B)(i)(II), and any additional information provided in subparagraph (B)(ii).

42 U.S.C. § 300gg-111(c)(5)(C)(i). As incorporated in subsection II above, "clause (ii)" lists the following five factors that the IDR entity "shall" consider:

> (I) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service (such as those endorsed by the consensus-based entity authority in section 1890 of the Social Security Act [42 U.S.C. 1395aaa]).
>
> (II) The market share held by the nonparticipating provider or facility or that of the plan or issuer in the geographic region in which the item or service was provided.
>
> (III) The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual.
>
> (IV) The teaching status, case mix, and scope of services of the non-participating facility that furnished such item or service.
>
> (V) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous four (4) plan years.

Id. § 300gg-111(c)(5)(C)(ii). Also as incorporated in subsection II above, the arbitrator must consider any information it requests from the parties, *id.* § 300gg-

111(c)(5)(C)(i)(II), as well as any additional information submitted by either party relating to its offer, *id.*

45.

Congress further specified three factors that the arbitrator "shall not consider": (1) usual and customary charges; (2) the amount the provider would have billed for the item or service if the Act's billing provisions did not apply; and (3) the amount a public payer (i.e., Medicare) would have paid. *Id.* § 300gg-111(c)(5)(D).

46.

The Act lists the above factors the arbitrator "shall consider" without giving presumptive weight to any single one. Although elsewhere Congress specifically delegated authority to the Secretaries to fill in gaps in the statute,[9] Congress did not

[9] *See* 42 U.S.C. § 300gg-111(c)(1)(B) (the notification initiating the IDR process must contain "such information as specified by the Secretary" and the process begins upon submission of the notification or "such other date specified by the Secretary"); *id.* § 300gg-111(c)(3)(A) ("the Secretary shall specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination . . . ."); *id.* § 300gg-111(c)(3)(A)(iv) (batched items and services must be furnished during a 30-day period "or an alternative period as determined by the Secretary"); *id.* § 300gg-111(c)(3)(B) ("the Secretary shall provide" for the treatment of bundled payments); *id.* § 300gg-111(c)(4)(A) ("The Secretary . . . shall establish a process to certify" IDR entities); *id.* § 300gg-111(c)(4)(A)(vii) (the IDR entity must meet specified requirements and "such other requirements as determined appropriate by the Secretary"); *id.* § 300gg-111(c)(4)(F) ("The Secretary shall . . . provide for a method" for selecting a certified IDR entity); *id.* § 300gg-111(c)(7)(C) (to be certified, IDR entities must "submit to the Secretary

specifically assign the Departments any role in determining how the Subparagraph C Factors should be considered. Congress mandated that the arbitrator must consider each of these factors in determining which offer to select and purposefully left it to the discretion and expertise of the arbitrator to decide how much weight to give each factor in accordance with the facts and circumstances of each individual case.

47.

This, of course, was intentional. "Multiple proposals that ultimately did not become law relied on the median in-network rate [effectively, the QPA] as the benchmark for payment, with baseball-style arbitration designed as a backstop to, at most, result in a mere adjustment to the benchmark rate." Neal and Brady Letter; *see, e.g.*, Ban Surprise Bill Act, H.R. 5800, 116th Cong. § 2(a) (2020); Lower Health Care Costs Act, S. 1895, 116th Cong. § 103(a) (2019); No Surprises Act, H.R. 3630, 116th Cong. § 2(a) (2019). Congress considered and rejected these proposals.

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such information as the Secretary determines necessary to carry out the provisions of this subsection"); *id.* § 300gg-111(c)(7)(D) ("The Secretary shall ensure the public reporting" does not disclose privileged or confidential information); *id.* § 300gg-111(c)(8)(A) (fees for participating in the IDR process shall be paid "at such time and in such manner as specified by the Secretary"); *id.* § 300gg-111(c)(8)(B) (the amount of the fee is to be "an amount established by the Secretary"); *id.* § 300gg-111(c)(9) ("[t]he Secretary may modify" deadlines or timing requirements "in cases of extenuating circumstances, as specified by the Secretary").

Instead, in a bipartisan, bicameral compromise, Congress set forth a detailed scheme of factors the arbitrator must (and must not) consider.

48.

The Act provides that an arbitrator's decision is not subject to judicial review. 42 U.S.C. § 300gg-111(c)(5)(E)(i)(II).

D. Timeline for Implementing Relevant Regulations

49.

The Act required the Departments to issue implementing regulations on certain issues by specified deadlines.

50.

By July 1, 2021, the Departments were required to establish the methodology that insurers shall use to determine the QPA, including the geographic regions for such calculations; the information insurers should share with providers about how they calculated QPAs; and a process for receiving complaints about insurers' alleged violations of the rules for calculating QPAs. 42 U.S.C. § 300gg-111(a)(2)(B).

51.

By December 27, 2021, the Departments are required to establish, among other things, the IDR process for resolving disputes between insurers and providers regarding out-of-network payment. 42 U.S.C. § 300gg-111(c)(2)(A).

E. Implementing Rulemaking and Guidance

1. July 1, 2021 Interim Final Rule ("July Rule")

52.

On July 1, 2021, the Departments made publicly available an interim final rule with comment to implement certain surprise billing requirements of the Act. This regulation was published in the Federal Register on July 13 and was effective on September 13, 2021. 86 Fed. Reg. 36,872 (July 13, 2021).

53.

Among other provisions, the July Rule set forth a methodology for how payors were to calculate QPAs, 45 C.F.R. § 149.140(c), and the information payors must share with out-of-network providers relating to how they calculated QPAs, *id*.§ 149.140(d). These provisions were subject to a rulemaking deadline in the No Surprises Act of July 1, 2021. 42 U.S.C. § 300gg-111(a)(2)(B); 86 Fed. Reg. at 36,918.

54.

The information payors use to calculate QPAs lies solely within their control, and the mandatory disclosures related to QPAs are wholly insufficient to allow the Departments, the IDR entities, and, critically, providers to ascertain whether a payor has correctly calculated the QPA. When payors are not bound by an applicable All-

Payer Model Agreement or specified state law, the Departments require them to share only the following information about the QPA when issuing an initial payment or notice of denial of payment to a healthcare provider:

> (1) the actual QPA amount for each item or service involved;
>
> (2) a statement certifying that the QPA applies and was accurately calculated in compliance with the Departments' methodology;
>
> (3) a statement indicating that the healthcare provider can initiate a 30-day open negotiation period, and if those negotiations fail, the healthcare provider can initiate the IDR process; and
>
> (4) contact information for a person who can begin open negotiations on behalf of the payor. 45 C.F.R. § 149.140(d)(1)(iv).

Upon request of a healthcare provider, payors must also provide:

> (1) information about whether the QPA was calculated using contracted rates that were not fee-for-service and, if so, whether the QPA was determined using underlying fee schedule rates or a derived amount;
>
> (2) if the payor used an independent database to determine the QPA, which database was used;
>
> (3) if a related service code was used to determine the QPA, which service code was used; and

(4) if applicable, a statement that the payor's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved that were excluded for purposes of calculating the QPA. *Id*. § 149.140(d)(2).

55.

This information is insufficient to allow healthcare providers to verify the accuracy of the certification they receive from plans and issuers representing that all relevant QPAs were correctly calculated.

56.

The July Rule noted that HHS would amend its enforcement regulations through further notice-and-comment rulemaking to reflect the amendments made to the PHS Act by the Act, but that HHS and the other government agencies would generally use their existing enforcement processes to police compliance with the Act's provisions. 86 Fed. Reg. at 36,899. HHS has primary enforcement authority over issuers only if the Secretary of HHS make a determination that a state is failing to substantially enforce a provision of the Act, and HHS plans to conduct no more than nine audits annually. *Id*. at 36,935.

2. August 20, 2021 FAQs

57.

On August 20, 2021, the Departments of HHS, Labor, and the Treasury issued a guidance document, in the form of a series of FAQs, addressing a number of topics relating to the obligations imposed by the Act. *See* DEP'TS, *FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49* (Aug. 20, 2021).[10]

58.

In these FAQs, the Departments announced that they would, as a matter of discretion, delay enforcement of several provisions of the Act until they could finalize implementing regulations. The Departments announced that they would defer enforcement of the requirement that payors make available a price comparison tool (by internet website, in paper form, or telephone) by an additional year, until January 1, 2023, following the completion of notice-and-comment rulemaking. *Id.* at 3–4. The Departments recognized that it is "likely not possible" for regulated entities to come into compliance by January 1, 2022, with the No Surprises Act's

[10] DEP'TS, FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (Aug. 20, 2021), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

requirement that healthcare providers send a good faith estimate of the expected charges for scheduled items and services to insured patients planning to submit a claim for those items and services to their plan or issuer. *Id.* at 5–6. Accordingly, the Departments deferred enforcement of this requirement indefinitely, until the completion of future rulemaking. *Id.* Similarly, the Departments determined that it was "likely not possible" for plans and issuers to incorporate, by January 1, 2022, good faith estimates of expected charges in the advanced explanation of benefits they provide to patients. *Id.* at 6–7. Accordingly, the Departments deferred enforcement of this requirement until after "notice and comment rulemaking." *Id.*

59.

For other provisions, the Departments explained that they would not issue implementing regulations before those provisions' effective date of January 1, 2022 but clarified that regulated entities would still need to comply by that date, using a "good faith, reasonable interpretation of the statute." *Id.* at 8 (healthcare provider directory requirements); *id.* at 8–9 (balance billing disclosure requirements for payors); *id.* at 9 (continuity of care requirements).

3. September 10, 2021 Proposed Rulemaking

60.

On September 10, 2021, the Departments issued a joint notice of proposed rulemaking implementing provisions of the Act and other provisions of the Consolidated Appropriations Act, 2021. This proposed rule was published in the Federal Register on September 16, 2021, 86 Fed. Reg. 51,730 (Sept. 16, 2021), and concerned, among other provisions, the process by which HHS would investigate complaints and potential violations of the Act's requirements and take enforcement actions.

61.

The Act requires the Secretaries of HHS and the Treasury to establish this audit process through rulemaking "[n]ot later than October 1, 2021." 42 U.S.C. § 300gg-111(a)(2)(A). The comment period for this proposed rule closed on October 18, 2021. 86 Fed. Reg. at 51,730.

4. The September Rule

62.

On September 30, 2021, the Departments publicly released the Interim Final Rule at issue here. Among other things, this Rule establishes regulations governing the IDR process, as well as the arbitrator's determination of the appropriate out-of-

network payment rate. This Rule was published in the Federal Register on October 7, 2021, and become effective on that date. 86 Fed. Reg. 55,980.

63.

The September Rule mandates that the arbitrator employ a "rebuttable presumption" that the offer closest to the QPA represents the appropriate reimbursement amount. Specifically, the arbitrator "must select the offer closest to the [QPA] unless the certified IDR entity determines that credible information submitted by either party . . . clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate." Id. at 56,104. "[I]f the offers are equally distant from the [QPA] but in opposing directions," then "the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer." *Id*.

64.

Therefore, under the September Rule, the arbitrator must select the offer closest to the QPA unless "credible information" regarding the additional statutory factors "rebuts that presumption" and "clearly demonstrates" that the QPA is "materially different" from the appropriate out-of-network rate. *Id*. A "material difference" exists "where there is substantial likelihood that a reasonable person with

the training and qualifications of a certified IDR entity making a payment determination would consider the information important in determining the out-of-network rate and view the information as showing that the QPA is not the appropriate out-of-network rate." *Id*. at 55,995.

65.

As a result of this new presumption, even if an arbitrator concludes, after considering all the factors Congress directed it to consider in each individual case, that the offer farther from the QPA better reflects the value of the services provided and is the appropriate payment amount, the arbitrator may not select that offer unless its proponent satisfies the heightened burden set forth in the September Rule.

66.

If the arbitrator does select the offer farther from the QPA, it must provide in its written decision "a detailed explanation" justifying its decision to reject the offer closer to the QPA. *Id*. at 56,000. That detailed explanation must describe "the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate." *Id*.

67.

As a result, contrary to the Act, the September Rule does not require the arbitrator to consider all Subparagraph C Factors "[i]n determining which offer" is the best. 42 U.S.C. § 300gg-111(c)(5)(C)(i).

68.

The Departments identified no statutory text creating these requirements or any gap or ambiguity in the Act's description of how an arbitrator should select an appropriate out-of-network rate. Instead, they asserted that the statute is "best interpret[ed]" to require arbitrators to employ a rebuttable presumption in favor of the QPA. *Id*. at 55,996.

69.

In support of their "interpretation," the Departments rely on several heretofore canons of construction, including that (i) "[t]he statutory text lists the QPA as the first factor," (ii) the other factors "are described in a separate paragraph" and are "subject to a prohibition on considering certain factors," and (iii) the statute "sets out detailed rules for calculating the QPA" and requires the QPA to be used in determining patient cost-sharing. *Id.* at 55,996. None of these features can overcome Congress's clear and direct text listing the "considerations" the arbitrator "shall" and "shall not" consider.

70.

The Departments also cited various "policy considerations," such as "increas[ing] the predictability of IDR outcomes," "encourag[ing] parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs," and "aid[ing] in reducing prices that *may* have been inflated due to the practice of surprise billing prior to [the Act]." 86 Fed. Reg. at 56,061 (emphasis added).

71.

With regard to the decision to issue the IDR regulations as an interim final rule, the Departments acknowledged that the APA requires notice and comment for legislative rules such as this one. *See* 5 U.S.C. § 553(b)(B); 86 Fed. Reg. at 56,043. They concluded, however, that "good cause" existed for bypassing that requirement. 86 Fed. Reg. at 56,043.

72.

The Departments conceded that the full year between the Act's enactment on December 27, 2020, and its effective date of January 1, 2022, "may have allowed for the regulations" to be finalized through notice-and-comment rulemaking before the Act took effect. *Id.* Nonetheless, the Departments asserted that it was "impracticable and contrary to the public interest to engage in full notice and comment rulemaking" before finalizing the September Rule because "this timeframe

would not provide sufficient time for the regulated entities to implement the requirements" relating to the IDR process. *Id.* at 56,044.

73.

Specifically, the Departments asserted that payors would need to take into account the IDR regulations as they finalize benefit designs, rates, and plan offerings, and that IDR entities would need time to apply for certification and be prepared to conduct payment determinations after January 1, 2022. *Id.* The Departments further asserted that without the rules established by the September Rule for initiating the IDR process and providing information to the IDR entity, providers "will not be able to resort to the Federal IDR process . . . leaving the possibility that they will be undercompensated for their services." *Id*.

74.

Nevertheless, the Departments did not state that it would have been impossible to provide notice and comment and finalize the IDR regulations by the Act's effective date. Contrary to Congress's judgment as reflected in the December 27, 2021 statutory deadline, the Departments did not explain why final IDR regulations issued by that date would give parties and IDR entities insufficient time to be ready to begin conducting arbitrations on schedule in March 2022. They also did not explain why the rebuttable presumption they created in favor of the QPA was

necessary for the IDR process to function or why it would have been impracticable or contrary to the public interest to provide notice and comment before imposing that requirement.

F. Anticipated Impact of the September Rule

75.

Georgia is one of several states that has implemented a state surprise medical billing law. For some claims, this will serve as the "specified state law" that will govern the healthcare provider out-of-network reimbursement. However, this law is not as comprehensive as the Act, and for many of out-of-network services, the Act's IDR process will be used to determine provider reimbursement. For example, the Georgia law does not cover self-insured health plans, under which the majority of private sector plan enrollees receive their benefits.[11]

76.

For claims subject to the Act, the unlawful presumption adopted in the September Rule will, by design, result in party offers and IDR decisions that cluster

[11] *See* Ga. Code Ann. § 33-20E-1 *et seq.* (2021), known as the "Surprise Billing Consumer Protection Act." GCEP was active in the development of this Act as part of its representation of the interests of emergency physicians and physician group. GCEP's efforts related to this Act were ultimately successful as it is fairly balanced and does not undercut the healthcare provider's leverage in insurer contract negotiations.

closer to the QPA than they otherwise would. *See* 86 Fed. Reg. at 56,061 (stating that the presumption in favor of the QPA "will encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA"). Restricting arbitrators' ability to weigh all factors as they deem appropriate and mandating that they cling to the QPA instead will skew IDR results in favor of payors and undermine providers' ability to obtain adequate compensation for their services.

77.

For a variety of reasons, the QPA will often be lower than the fair market value of providers' services as reflected by reimbursement amounts paid in the marketplace. First, in the July Rule, the Departments interpreted the phrase "median of contracted rates" to mean that each *contract* is a data point, rather than each *payment* made pursuant to a contract. *See* 96 Fed. Reg. at 36,889. The Departments could have calculated the median contracted rate as the median of payments made for each item or service, which would have more accurately approximated prevailing market rates. The Departments instead selected the median of contracts, concluding that the median of payments would "put upward pressure on the QPA." *Id.* at 36,930.

78.

Additionally, the Departments' methodology for calculating the QPA includes certain contracted rates that will often cause the QPA to understate the true market

value of providers' services. The Departments do not require that payors actually make a payment pursuant to a contract in order for that contracted rate to be incorporated into the QPA. For example, insurers may require primary care doctors to include rates for emergency room services in their contracts, even though they do not provide those services and thus lack the incentive to negotiate a true market rate. Yet the Departments not only count those rates in calculating the QPA but give them equal weight with rates that are used frequently.

79.

The Departments' QPA methodology also excludes important factors. The Departments excluded risk-sharing, bonus, and incentive payments from the QPA, even though they can amount to 10–15% of the total payment amount to physicians. In addition, the Departments' QPA methodology excludes the significant number of payments not made pursuant to a contract. Because there are limited rules regarding network adequacy for most hospital-based specialties, those services often are not covered by in-network contractual arrangements. The exclusion of these payments from the QPA will further deflate it compared to the true market value of providers' services.

80.

These flaws in the methodology for calculating the QPA are compounded by a lack of oversight. Payors are solely responsible for calculating and reporting QPAs. Providers have no visibility into how QPAs are calculated, and the government has announced little anticipated auditing of QPAs—despite statutory encouragement to do so. Providers will thus lack pertinent information to assess whether the insurer has calculated the QPA accurately, including whether the claim was downcoded (*i.e.*, the payor selected the QPA for a procedure with lower acuity and thus a lower reimbursement rate), the amount of any bonuses or supplemental payments not included in the QPA, the number of contracts and the number of providers included in the QPA, and the types of specialties that have contracted rates in the dataset used to determine the QPA.

81.

Other state surprise medical billing laws have set benchmarks that are similar to the QPA in that they are based on median contract rates as calculated solely by payors with little government oversight and no visibility by healthcare providers. Experience in these states has shown that tying arbitrations to a benchmark like the QPA drives down provider reimbursement.

82.

In 2017, for example, California passed AB72, 2016 Leg., Reg. Sess. (Cal. 2016), which sets reimbursement amounts based on the insurers' average contracted rates and creates an independent dispute resolution process for resolving disputes. Following passage of AB72, payors became more challenging to contract with. According to one survey, 31% of clinicians experienced insurers refusing to renew contracts, 23% had an existing contract terminated, and 71% were asked to accept rates below the cost to provide care.[12] At the same time, payors forced providers out of network and decreased their out-of-network reimbursement rates, recognizing that a below-market median rate would serve as the benchmark in arbitration. Survey results showed that 80% of physicians received reimbursement cuts of up to 30%, with 71% of emergency room physicians experiencing up to 30% rate cuts, and 22% of emergency room physicians experiencing 31–50% rate cuts.[13] Another study showed that the per-unit rates for anesthesiology services declined 13.64% for out-

[12] Cal. Med. Ass'n, *Surprise Billing Survey Results* 4 (rev. Nov. 1, 2019), https://www.cmadocs.org/Portals/CMA/files/public/CMA%20Suprise%20Billing%20Survey%20Results%202019.pdf?ver=2019-11-04-155222-927.

[13] *Id.*

of-network services and 10.75% for in-network services following the implementation of California's law.[14]

83.

A similar trend has already begun in response to the Act as indicated by Blue Cross Blue Shield North Carolina's correspondence to providers threatening to "terminate agreements" with providers who do not agree to lower rates in light of the new rule on grounds that "the Interim Final Rules provide enough clarity to warrant a significant reduction in your contracted rate with Blue Cross NC." Letter from Mark Werner, Blue Cross Blue Shield of North Carolina, to Provider (Nov. 5, 2021), https://tinyurl.com/y3dfvtts.

84.

The Departments' new "rebuttable presumption" in favor of the offer closest to the QPA during the IDR process will have similar results. Providers will often receive lower reimbursement that does not reflect the fair market value of their services, and some patients will lose access to their in-network physicians.

[14] Ambar La Forgia et al., *Association of Surprise-Billing Legislation with Prices Paid to In-Network and Out-of-Network Anesthesiologists in California, Florida, and New York: An Economic Analysis*, 181 JAMA Internal Med. 1324, 1328 tbl.2 (2021).

STATEMENT OF CLAIMS FOR RELIEF

COUNT I

THE SEPTEMBER RULE'S PRESUMPTION IN FAVOR OF THE QPA EXCEEDS THE DEFENDANTS' STATUTORY AUTHORITY AND IS NOT IN ACCORDANCE WITH LAW (5 U.S.C. § 706; 42 U.S.C. § 300gg-111(c); 29 U.S.C. § 1185e(c); 26 U.S.C. § 9816(c))

85.

The preceding paragraphs are incorporated by reference.

86.

The APA provides that courts will "hold unlawful and set aside agency action" that is "not in accordance with law." 5 U.S.C. § 706(2)(A).

87.

The Act exhaustively details the Subparagraph C Factors an arbitrator "shall consider" "[i]n determining which offer" to select. 42 U.S.C. § 300gg-111(c)(5)(C). The Act does not give any one of those factors priority or otherwise dictate how the arbitrator should weigh the factors. Instead, the Act requires the arbitrator to have "sufficient medical, legal, and other expertise" to determine how best to weigh the Subparagraph C Factors in light of the facts and circumstances of a particular case. *Id.* § 300gg-111(c)(4)(A). The September Rule unlawfully alters Congress's balanced approach by requiring arbitrators to select the offer closest to the QPA unless a party "clearly demonstrates that the QPA is materially different from the

appropriate out-of-network rate." 86 Fed. Reg. at 55,995. Contravening the discretion Congress gave the arbitrator, the Departments have unlawfully arrogated that discretion to themselves.

88.

The Departments' claim that the statute is "best interpret[ed]" to require IDR entities to employ a rebuttable presumption in favor of the offer closest to the QPA is untenable. No language in the statute can even arguably be "interpreted" to require IDR entities to select the offer closest to the QPA unless the opposing party carries the heightened burden the Departments imposed to "clearly demonstrate that the QPA is materially different" from the appropriate rate.

89.

Moreover, no such requirement can be found in between the statutory lines, particularly in a statute as prescriptive as this one. If Congress had intended IDR entities to begin with the presumption that the QPA is an appropriate reimbursement amount and to treat the additional factors as relevant only insofar as they clearly rebut that presumption, Congress would have said so. Congress knows how to create rebuttable presumptions when it wants to and, in fact, did so elsewhere in the

Consolidated Appropriations Act, 2021.[15] Congress chose not to do so with respect to the Subparagraph C Factors. That is especially telling here, because "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (citation omitted).

90.

Congress also knew how to establish the QPA as a "benchmark" for payment if it wanted to, as reflected in other bills related to surprise billing. *See, e.g.*, Lower Health Care Costs Act, S. 1895, 116th Cong. § 103(a) (2019) ("ESTABLISHMENT OF BENCHMARK.—A group health plan or health insurance issuer offering group or individual health insurance coverage shall pay facilities or practitioners furnishing services for which such facilities and practitioners are prohibited from billing enrollees under section 2719A(g), the median in-network rate[.]"); *see also, e.g.*, Ban Surprise Bill Act, H.R. 5800, 116th Cong. § 2(a) (2020); No Surprises Act, H.R.

[15] *See* Consolidated Appropriations Act, 2021, Section 226 (15 U.S.C. § 1116), "Rebuttable Presumption of Irreparable Harm" ("A plaintiff seeking any such injunction shall be entitled to a rebuttable presumption of irreparable harm upon a finding of a violation identified in this subsection[.]")

3630, 116th Cong. § 2(a) (2019). But it ultimately decided against doing so in the Act.

91.

The Departments' "interpretation" of the "Payments determination" provision of the Act is an impermissible attempt to rewrite statutory language. The Departments cannot defend their atextual reading on the ground that Congress was silent or ambiguous with respect to the weighting of the Subparagraph C Factors. Congress's detailed listing of the factors IDR entities "shall" and "shall not" consider left zero room for supplementation by the Departments.

92.

The Departments cannot take advantage of the fact that the Act was "not written in 'thou shalt not' terms," *i.e.*, terms that expressly bar the agencies from imposing their invented presumption on the independent arbitration process. *Bayou Lawn & Landscape Servs.v. Sec'y of Lab.*, 713 F.3d 1080, 1085 (11th Cir. 2013) ("[I]f congressional silence is a sufficient basis upon which an agency may build a rulemaking authority, the relationship between the executive and legislative branches would undergo a fundamental change and agencies would enjoy virtually limitless hegemony . . . .'").

93.

The Departments cannot claim that Congress specifically delegated authority to the Departments to promulgate rules governing how an arbitrator should select an offer, as Congress did with other aspects of the Act. For example, the Act specifically authorizes the Departments to "establish a process to certify . . . [IDR] entities under this paragraph." 42 U.S.C. § 300gg-111(c)(4)(A). Likewise, the Act specifically provides that, in addition to four statutorily mandated criteria, the Departments "shall specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity." *Id.* at § 300gg-111(c)(3)(A). Congress thus specifically delegated authority to the Departments to supplement statutorily mandated criteria found elsewhere in the Act, yet Congress did not do the same in prescribing the Subparagraph C Factors. *See id.* § 300gg-111(c)(5) ("Not later than 30 days after the date of selection of the certified IDR entity . . ., the certified IDR entity shall," "taking into account the [Subparagraph C Factors]," select one of the offers.); *Russello*, 464 U.S. at 23. In any case, the Departments have in fact disclaimed any such delegation by insisting—erroneously—that all they have provided is the "best interpretation" of the statute. 86 Fed. Reg. at 55,996.

94.

Defendants cannot defend their "interpretation" of the Act under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). Not only is there no specific delegation in the Act, and not only is the Departments' interpretation foreclosed by the "unambiguously expressed intent" of Congress in the plain text of the statute, *id*. at 843, but the September Rule also is "procedurally defective." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001)). The APA requires federal agencies to provide public notice of proposed rules and an opportunity for comment, unless the agencies "for good cause" find that notice and comment "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B).[16] But the Departments cannot satisfy the high bar necessary to establish "good cause" here, as outlined in more detail below. Because Defendants failed "to

[16] HHS Secretary Xavier Becerra in fact "guarantee[d]" that before HHS took any action on the Act, it would "take the comments necessary, hear from all the stakeholders to make sure what we're doing is based on the facts, the science, and the law." Health and Human Services Department Fiscal Year 2022 Budget Request before the House Appropriations Sub-Committee (Apr. 15, 2021), https://www.c-span.org/video/?c4980111/userclip-becerra-statements-health-human-services-budget-request (at minute 49:06). The Departments did not keep this promise.

follow the correct procedures in issuing the regulation," "*Chevron* deference is not warranted." *Encino Motorcars, LLC*, 579 U.S. at 220.

95.

The Departments' attempt to override the language of the statute and upset the balanced approach that Congress required the arbitrator to follow when making payment determinations is *ultra vires* and contrary to the No Surprises Act.

COUNT II

THE DEFENDANTS UNLAWFULLY ISSUED THE SEPTEMBER RULE WITHOUT THE NOTICE AND COMMENT REQUIRED BY THE APA (5 U.S.C. §§ 553, 706)

96.

The preceding paragraphs are incorporated by reference.

97.

The APA requires federal agencies to provide public notice of proposed rules and an opportunity for comment unless the agencies "for good cause" find that notice and comment "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B).

98.

This fundamental procedural protection of the APA is designed to ensure that members of the public have notice of proposed regulations that may impact their

interests and an opportunity to present their views to the agency—both to inform and improve the agency's decision-making and to promote public confidence in the administrative process.

99.

Accordingly, notice and comment are required for legislative rules in all but exceptional circumstances. While the APA permits agencies to bypass notice and comment for "good cause," this is a narrow exception reserved for emergency situations in which delay would cause serious harm and interfere with the agency's ability to carry out its statutory mandate.

100.

The Departments cannot satisfy the high bar necessary to establish good cause. Congress gave the Departments *an entire year* to promulgate IDR regulations. That is an abundance of time to formulate proposed rules and provide notice and opportunity for comment. The Departments cannot rely on their own delays to create an exigency establishing good cause.

101.

In any event, there was no exigency that could justify dispensing with notice and comment. The first arbitrations will not occur until at least March 2022. Had the Departments promulgated the September Rule as a proposed rule and sought

comment, they could easily have finalized a rule with sufficient time for the IDR process to begin functioning on schedule in March 2022. Indeed, by setting a December 27, 2021 deadline for the final IDR rules, Congress determined that there would be sufficient time to stand up the IDR process if final rules issued by that date. If more time was necessary, Congress would have set an earlier deadline, as it did elsewhere in the Act. Yet the Departments issued the September Rule three months before the statutory deadline, when they could have used that time to provide notice and comment.

102.

At a minimum, there was no justification for failing to provide notice and comment before issuing the rules establishing the rebuttable presumption in favor of the QPA. Even if IDR entities needed guidance from the Departments as to the standard to be applied in determining which party's offer to select—which they do not, as the statute is self-executing in that regard—they would not need that guidance any sooner than March 2022 when they will first begin hearing cases. Notice and comment could easily have been provided.

103.

Accordingly, there was no good cause for circumventing notice and comment, and the provisions of the September Rule creating the presumption in favor of the

offer closest to the QPA were issued "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully request that this Court enter judgment in its favor and grant the following relief:

(1) A declaration that the Departments acted unlawfully in (a) promulgating the provisions of the September Rule requiring IDR entities to employ a presumption in favor of the offer closest to the QPA, and (b) doing so without providing public notice and comment;

(2) An order vacating the provisions of the September Rule requiring IDR entities to employ a presumption in favor of the offer closest to the QPA:

(a) 45 C.F.R. § 149.510(a)(2)(v); 45 C.F.R. § 149.510(a)(2)(viii); the second and third sentences of 45 C.F.R. § 149.510(c)(4)(ii)(A); the final sentence of 45 C.F.R. § 149.510(c)(4)(iii)(C); 45 C.F.R. § 149.510(c)(4)(iv); and 45 C.F.R. § 149. 510(c)(4)(vi)(B).

(b) 26 C.F.R. § 54.9816-8T(a)(2)(v); 26 C.F.R. § 54.9816-8T(a)(2)(viii); the second and third sentences of 26 C.F.R. § 54.9816-8T(c)(4)(ii)(A); the final sentence of 26 C.F.R. § 54.9816-8T(c)(4)(iii)(C); 26 C.F.R. § 54.9816-8T(c)(4)(iv); and 26 C.F.R. § 54.9816-8T(c)(4)(vi)(B).

(c) 29 C.F.R. § 2590.716-8(a)(2)(v); 29 C.F.R. § 2590.716-8(a)(2)(viii); the second and third sentences of 29 C.F.R. § 2590.716-8(c)(4)(ii)(A); the final sentence of 29 C.F.R. § 2590.716-8(c)(4)(iii)(C); 29 C.F.R. § 2590.716-8(c)(4)(iv); and 29 C.F.R. § 2590.716-8(c)(4)(vi)(B).

(3) An injunction barring the Departments from enforcing the foregoing provisions;

(4) An injunction barring the Departments from promulgating replacement provisions without notice and comment;

(5) Attorney's fees and costs pursuant to 28 U.S.C. § 2412; and

(6) Any other just and proper relief.

Respectfully submitted this 23rd day of December, 2021.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

GEORGIA COLLEGE OF EMERGENCY PHYSICIANS and BRETT CANNON, M.D., Plaintiffs, vs. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, OFFICE OF PERSONNEL MANAGEMENT, and the CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES, Defendants.	CIVIL ACTION NO. _____

CERTIFICATE OF COMPLIANCE

The foregoing **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** is double-spaced in 14 point Times New Roman font and complies with the type-volume limitation set forth in Local Rule 7.1.

Respectfully submitted this 23rd day of December, 2021.

HALL BOOTH SMITH, P.C.

/s/ Brittany H. Cone
BRITTANY H. CONE
Georgia Bar No. 488550
S. DAVID MCLEAN, JR.
Georgia Bar No. 496890
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

GEORGIA COLLEGE OF EMERGENCY PHYSICIANS and BRETT CANNON, M.D., Plaintiffs, vs. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, OFFICE OF PERSONNEL MANAGEMENT, and the CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES, Defendants.	CIVIL ACTION NO. _____

CERTIFICATE OF SERVICE

I hereby certify that I have this day served a copy of the within and foregoing **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** with the Clerk of Court using the CM/ECF system, which will automatically send email notification of such filing to the following parties of record below, and by sending a true copy of the same to all parties of record and nonparties listed below by

certified/registered mail, with adequate postage affixed thereon, addressed as follows:

Civil Process Clerk
United States Attorney's Office
555 Fourth Street, N.W.
Washington, D.C. 20530

Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001

U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

U.S. Department of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

U.S. Office of Personnel Management
1900 E. Street, N.W.
Washington, D.C. 20415-1000

Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Martin J. Walsh
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Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, N.W.
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Kiran Ahuja
Director of the U.S. Office of Personnel Management
1900 E. Street, N.W.
Washington, D.C. 20415-1000

The following nonparty was served by personal service in compliance with Federal Rule of Civil Procedure 4(i)(1)(A):

U.S. Attorney's Office for the Northern District of Georgia
Richard B. Russell Federal Building
75 Ted Turner Drive, S.W.
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Atlanta, GA 30303-3309

Respectfully submitted this 23rd day of December, 2021.

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